

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: <u>October 27, 2009</u> <i>(use as many sheets as necessary)</i>				Application Number	10/500,296
				Filing Date	January 6, 2003
				First Named Inventor	Yuji YAMAZAKI
				Art Unit	1644
				Examiner Name	Zachary S. SKELDING
Sheet	1	of	8	Attorney Docket Number	081356-0218

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	C1	5,585,089	12-17-1996	QUEEN et al.	
	C2	5,958,879 A	09-28-1999	KOPCHICK et al.	
	C3	6,001,358	12-14-1999	BLACK et al.	
	C4	6,617,118	09-09-2003	ROFFLER et al.	
	C5	7,094,551 B2	08-22-2006	ZAHRADNIK et al.	
	C6	7,223,563 B2	05-29-2007	ECONS et al.	
	C7	7,314,618 B2	01-01-2008	ECONS et al.	
	C8	2004/0171825 A1	09-02-2004	BOUGUELERET et al.	
	C9	2009/0110677 A1	04-30-2009	YAMASHITA et al.	
	C10	2009/0148461 A1	06-11-2009	YAMASHITA et al.	

UNPUBLISHED U.S. PATENT APPLICATION DOCUMENTS					
Examiner Initials*	Cite No. ¹	U.S. Patent Application Document	Filing Date of Cited Document MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Serial Number-Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	C11	CA 2418215	01-31-2002	ADVANCED RESEARCH & TECHNOLOGY INSTITUTE et al.		
	C12	EP 120694	10-03-1984	BOSS et al.		
	C13	EP 125023	11-14-1984	CABILLY et al.		
	C14	EP 1466925 A1	10-13-2004	YAMAZAKI et al.		
	C15	EP 0314161 A1	10-28-1988	HARRIS et al.		
	C16	GB 2188638A	10-07-1987	WINTER et al.		
	C17	JP S-61-178926	11-08-1986	TADASHI et al.		
	C18	JP H-02-117920	02-05-1990	AKIHIKO et al.		

Examiner Signature		Date Considered	
---------------------------	--	------------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: <u>October 27, 2009</u> <i>(use as many sheets as necessary)</i>				Application Number	10/500,296
				Filing Date	January 6, 2003
				First Named Inventor	Yuji YAMAZAKI
				Art Unit	1644
				Examiner Name	Zachary S. SKELDING
Sheet	2	of	8	Attorney Docket Number	081356-0218

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	C19	WO 99/60017	11-25-1999	UNIVERSITY COLLEGE LONDON		
	C20	WO 00/10383	03-02-2000	TOMIZUKA et al.		
	C21	WO 00/60085 A1	10-12-2000	MILLENNIUM PHARMACEUTICALS, INC.		
	C22	WO 00/73454 A1	12-07-2000	GENENTECH, INC.		
	C23	WO 01/40466 A2	06-07-2001	GENENTECH, INC.		
	C24	WO 01/42451 A2	06-14-2001	GENSET		
	C25	WO 01/60850 A1	08-23-2001	SMITHKLINE BEECHAM CORPORATION & SMITHKLINE BEECHAM P.L.C.		
	C26	WO 02/08271 A1	01-31-2002	ECONS et al.		
	C27	WO 02/088358 A2	11-07-2002	BOUGUELERET et al.		
	C28	WO 2002/43478	05-27-2004	MEDAREX, Inc.		
	C29	WO 2006/78072 A1	07-27-2006	TOMIZUKA et al.		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	C30	Non-Final Office Action for U.S. Application No. 10/344,339 dated January 18, 2008.	
	C31	Advisory Action for U.S. Application No. 10/344,339 dated December 7, 2007.	
	C32	Final Office Action for U.S. Application No. 10/344,339 dated June 22, 2007.	
	C33	Non-Final Office Action for U.S. Application No. 10/344,339 dated September 27, 2006.	
	C34	Notice of Allowance for Korean Patent Application No. 10-2003-7001931 dated November 26, 2008 – international, counterpart to U.S. Application No. 10/344,339. <i>(No English-language Translation Available)</i>	
	C35	Office Action for Canadian Patent Application No. 2,418,802 dated February 13, 2009 – international, counterpart to U.S. Application No. 10/344,339.	

Examiner Signature		Date Considered	
---------------------------	--	------------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: <u>October 27, 2009</u> (use as many sheets as necessary)		Application Number	10/500,296
		Filing Date	January 6, 2003
		First Named Inventor	Yuji YAMAZAKI
		Art Unit	1644
		Examiner Name	Zachary S. SKELDING
Sheet	3	of	8
		Attorney Docket Number	081356-0218

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	C36	Supplementary European Search Report of European Patent Application No. EP 01 95 8379 dated May 27, 2005 – international, counterpart to U.S. Application No. 10/344,339.	
	C37	International Search Report of PCT Patent Application No. PCT/JP2008/052918 dated March 13, 2008 – international, counterpart to U.S. Application No. 12/030,593.	
	C38	AONO et al., "The improving effect of anti FGF23 neutralizing antibody on hypophosphatemia and rickets of Hyp mice", <i>The Japanese Society for Bone and Mineral Research (JSBMR)</i> , Annual Meeting of the JSBMR, 22 nd Program, August 2004, Vol. 22, pp.137. (English translation provided)	
	C39	ANDO, et al., <i>Tan-Clone-Kotai-Jikken-Manual</i> ("Experimental Manual for Monoclonal Antibody") (written by and published by Kodansha Scientific, Ltd., Tokyo, Japan (1991))	
	C40	Antibody Engineering, A Practical Approach, IRL Press, 1996	
	C41	Antibody Engineering, A Practical Guide, W.H. Freeman and Company, 1992.	
	C42	ASCHINBERG et al., "Vitamin D-resistant rickets associated with epidermal nevus syndrome: Demonstration of a phosphaturic substance in the dermal lesions," <i>The Journal of Pediatrics</i> , Vol. 91, No. 1, July 1997, pp. 56-60, The C.V. Mosby Company, St. Louis, Mo.	
	C43	BAKER and WORTHLEY, "The Essentials of Calcium, Magnesium and Phosphate Metabolism: Part II. Disorders," <i>Critical Care & Resuscitation.</i> , 2000, Vol. 4, pp. 307-315.	
	C44	BETTER et al., " <i>Escherichia coli</i> Secretion of an Active Chimeric Antibody Fragment," <i>Science</i> , May 20, 1998 (nti), Vol. 240, pp. 1041-1043.	
	C45	BENJANNET et al., "α1-Antitrypsin Portland Inhibits Processing of Precursors Mediated by Proprotein Convertases Primarily within the constitutive Secretory Pathway," <i>The Journal of Biological Chemistry</i> , Vol. 272, No. 42, October 17, 1997, pp. 2610-2618, The American Society for Biochemistry and Molecular Biology, Inc.	
	C46	BRIAND et al., "Application and limitations of the multiple antigen peptide (MAP) system in the production and evaluation of anti-peptide and anti-protein antibodies", <i>Journal of Immunological Methods</i> , Vol. 156, No. 2, 1992, pp. 255-265, Elsevier Science Publishers B.V.	
	C47	BRUGGEMANN, et al., "The Immunogenicity of Chimeric Antibodies", <i>J. Exp. Med.</i> , December 1989, Vol. 170, No. 6, pp. 2153-2157.	
	C48	CAI et al., "Brief Report: Inhibition of Renal Phosphate Transport by a Tumor Product in a Patient with Oncogenic Osteomalacia", <i>The New England Journal of Medicine</i> , Vol. 330, No. 23, June 9, 1994, pages 1645-1649, The Massachusetts Medical Society.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: <u>October 27, 2009</u> (use as many sheets as necessary)		Application Number	10/500,296
		Filing Date	January 6, 2003
		First Named Inventor	Yuji YAMAZAKI
		Art Unit	1644
		Examiner Name	Zachary S. SKELDING
Sheet	4	of	8
		Attorney Docket Number	081356-0218

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	C49	CARTER, et al., "High Level <i>Escherichia coli</i> Expression and Production of a Bivalent Humanized Antibody Fragment," <i>Bio/Technology</i> , 1992, Vol. 10, pp. 163-167.	
	C50	DELVES, P. J., "Antibody Production Essential Techniques", <i>Monoclonal Antibodies</i> , Ed. Shepherd and Dean, Oxford University Press, 2000.	
	C51	DREZNER, "PHEX gene and hypophosphatemia", <i>Kidney International</i> , Vol. 57, No. 1, January 2000, pages 9-18, The International Society of Nephrology.	
	C52	ECAROT et al., "Defective Bone Formation by Hyp Mouse Bone cells Transplanted into Normal Mice: Evidence in Favor of an Intrinsic Osteoblast Defect", <i>Journal of Bone and Mineral Research</i> , Vol. 7, No. 2, February 1992, pp. 215-220, Mary Ann Liebert, Inc.	
	C53	ECONS et al., "Autosomal Dominant Hypophosphatemic Rickets Is Linked to Chromosome 12p13", <i>The Journal of Clinical Investigation</i> , Vol. 100, No. 11, December 1, 1997, pp. 2653-2657, The Rockefeller University Press.	
	C54	ECONS et al., "Tumor-Induced Osteomalacia- Unveiling a New Hormone", <i>The New England Journal of Medicine</i> , Vol. 330, No. 23, June 9, 1994, PP. 1679-1681, The Massachusetts Medical Society.	
	C55	ECONS, "New Insights Into The Pathogenesis Of Inherited Phosphate Wasting Disorders" <i>Bone</i> , Vol. 25, No. 1, July 1999, pp. 131-135 PERGAMON PRESS, Oxford, GB.	
	C56	FISHWILD, et al., "High-avidity Human IgGκ Monoclonal Antibodies from a Novel Strain of Minilocus Transgenic Mice," <i>Nat Biotechnol.</i> , July 1996, Vol. 14, No. 7, pp. 845-851.	
	C57	FUKAGAWA, et al., "FGF23: its Role in Renal Bone Disease", <i>Pediat. Nephrol.</i> , 2006, Vol. 21, pp. 1802-1806.	
	C58	FUKUMOTO et al., "Diagnostic Utility of Magnetic Resonance Imaging Skeletal Survey in a Patient With Oncogenic Osteomalacia", <i>Bone</i> , Vol. 25, No. 3, September 1999, pp. 375-377, Elsevier.	
	C59	GODING, J. W., <i>Monoclonal Antibodies: Principles and Practice</i> , Academic Press, 1993 and 1995.	
	C60	GUPTA, et al., "FGF-23 is Elevated by Chronic Hyperphosphatemia," <i>J. Clin. Endocrinol. & Metab.</i> , 2004. Vol. 89, No. 9, pp. 4489-4492.	
	C61	HAN et al., "Epinephrine translocates GLUT-4 but inhibits insulin-stimulated glucose transport in rat muscle", <i>American Journal of Physiology</i> , Vol. 274, No. 4, April 1998, p. E700-7, The American Physiological Society.	
	C62	IMEL, et al., "FGF23 Concentrations Vary with Disease Status in Autosomal Dominant Hypophosphatemic Rickets," <i>J. of Bone and Mineral Research</i> , 2007, Vol. 22, pp. 520-526.	

Examiner Signature	Date Considered
---------------------------	------------------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: <u>October 27, 2009</u> (use as many sheets as necessary)		Application Number	10/500,296
		Filing Date	January 6, 2003
		First Named Inventor	Yuji YAMAZAKI
		Art Unit	1644
		Examiner Name	Zachary S. SKELDING
Sheet	5	of	8
		Attorney Docket Number	081356-0218

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	C63	ISHIDA & LONBERG, IBC's 11th Antibody Engineering, Abstract 2000.	
	C64	JONSSON, et al., "Fibroblast Growth Factor 23 in Oncogenic Osteomalacia and X-Linked Hypophosphatemia," <i>N. Engl. J. Med.</i> , April 24, 2003, Vol. 348, No. 17, pp. 1656-1663.	
	C65	KARLSSON, et al., "Kinetic Analysis of Monoclonal Antibody-Antigen Interactions with a New Biosensor Based Analytical System," <i>Journal of Immunological Methods</i> , 1991, Vol. 145, pp. 229-240.	
	C66	KEARNEY, et al., "A New Mouse Myeloma Cell Line that has Lost Immunoglobulin Expression but Permits the Construction of Antibody-Secreting Hybrid Cell Lines", <i>J. Immunology</i> , September 1979, Vol. 123, No. 3, pp. 1548-1550.	
	C67	KESSLER et al., "A Modified Procedure For The Rapid Preparation OF Efficiently Transporin Vesicles From Small Intestinal Brush Border Membranes", <i>Biochimica et Biophysica Acta</i> , Vol. 506, No. 1, January 4, 1978, pp. 136-155, Elsevier/North-Holland Biomedical Press.	
	C68	KING, D.J., <i>Applications and Engineering of Monoclonal Antibodies</i> , T. J. International Ltd, 1998.	
	C69	KITAMURA, et al., "A B Cell-deficient Mouse by Targeted Distribution of the Membrane Exon of the Immunoglobulin μ Chain Gene," <i>Nature</i> , 1991, Vol. 350, No. 4, pp. 423-426.	
	C70	KOHLER, et al., "Derivation of Specific Antibody-producing Tissue Culture and Tumor Lines by Cell Fusion", <i>European J. Immunology</i> , 1966, Vol. 6, pp. 511-519.	
	C71	LAH, et al., "Phage Surface Presentation and Secretion of Antibody Fragments using an Adaptable Phagemid Vector," <i>Human Antibodies & Hybridomas</i> , 1994, Vol. 5, Nos. 1 and 2, pp. 48-56.	
	C72	LAJEUNESSE et al., "Direct demonstration of a humorally-mediated inhibition of renal phosphate transport in the <i>Hyp</i> mouse", <i>Kidney International</i> , Vol. 50, No. 5, November 1996, pp. 1531-8, The International Society of Nephrology.	
	C73	LARSSON, et al., "Circulating Concentration of FGF-23 Increases as Renal Function Declines in Patients with Chronic Kidney Disease, but does not Change in Response to Variation in Phosphate Intake in Healthy Volunteers," <i>Kidney International</i> , 2003, Vol. 64, pp. 2272-2279.	
	C74	LAU et al., "Evidence for a Humoral Phosphaturic Factor in Oncogenic Hypophosphatemic Osteomalacia", <i>Clinical Research</i> , Vol. 27, No. 2, April 1979, page 421A.	
	C75	LORENZ-DEPIEREUX et al., "Autosomal Dominant Hypophosphatemic Rickets (ADHR) Is Caused By Mutations In A Gene Encoding A Novel Member of the Fibroblast Growth Factor Family(FGF-21)" <i>American Journal of Human Genetics</i> , vol. 67, no. 4, suppl. 2, October 2000, pg. 12.	
	C76	LORENZ-DEPIEREUX, et al., "DMP1 Mutations in Autosomal Recessive Hypophosphatemia Implicate a Bone Matrix Protein in the Regulation of Phosphate Homeostasis," <i>Nature Genetics</i> , November 2006, Vol. 38, No. 11, pp. 1248-1250.	

Examiner Signature		Date Considered	
---------------------------	--	------------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: <u>October 27, 2009</u> (use as many sheets as necessary)		Application Number	10/500,296
		Filing Date	January 6, 2003
		First Named Inventor	Yuji YAMAZAKI
		Art Unit	1644
		Examiner Name	Zachary S. SKELDING
Sheet	6	of	8
		Attorney Docket Number	081356-0218

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	C77	LU et al., "Chemically Unambiguous Peptide Immunogen: Preparation, Orientation and Antigenicity of Purified Peptide Conjugated to the Multiple Antigen Peptide System", <i>Molecular Immunology</i> , Vol. 28, No. 6, June 1991, pp. 623-630, Pergamon Press, Great Britain.	
	C78	MARK, et al., "Site-specific Mutagenesis of the Human Fibroblast Interferon Gene", <i>Proc Natl Acad Sci U.S.A.</i> , September 1984, Vol. 81, No. 18, pp. 5662-5666.	
	C79	MEYER et al., "Parabiosis Suggests a Humoral Factor Is Involved in X-Linked Hypophosphatemia in Mice", <i>Journal of Bone and Mineral Research</i> , Vol. 4, No. 4, August 1989, pp. 493-500, Mary Ann Leibert, Inc.	
	C80	MIYAUCHI et al., "Hemangiopericytoma-Induced Osteomalacia: Tumor Transplantation in Nude Mice Causes Hypophosphatemia and Tumor Extracts Inhibit Renal 25-Hydroxyvitamin D 1-Hydroxylase Activity", <i>Journal of Clinical Endocrinology and Metabolism</i> , Vol. 67, No. 1, July 1988, pp. 46-53, The Endocrine Society.	
	C81	NCBI GenBank Accession No. NP_065689 (March 25, 2007)	
	C82	NCBI GenBank Accession No. NM_020638 (March 25, 2007)	
	C83	NCBI GenBank Accession No. AY566236 (March 16, 2004)	
	C84	NELSON et al., "Oncogenic osteomalacia: is there a new phosphate regulating hormone?", <i>Clinical Endocrinology</i> , Vol. 47, No. 6, December 1997, pp. 635-42, Blackwell Science Ltd.	
	C85	NYKJAER et al., "An Endocytic Pathway Essential for Renal Uptake and Activation of the Steroid 25-(OH) Vitamin D ₃ ", <i>Cell</i> , Vol. 96, No. 4, February 19, 1999, pp. 507-15, Cell Press.	
	C86	ORNITZ, et al., "Fibroblast Growth Factors," <i>Genome Biology</i> , 2001, Vol. 2, No. 3, pp. 3005.1-3005.12.	
	C87	POPOVTZER et al., "Tumor-Induced Hypophosphatemic Osteomalacia (TUO): Evidence for a Phosphaturic Cyclic AMP-Independent Action of Tumor Extract", <i>Clinical Research</i> , Vol. 29, No. 2, April 1981, p. 418A.	
	C88	POSNETT et al., "A Novel Method for Producing Anti-peptide Antibodies", <i>The Journal of Biological Chemistry</i> , Vol. 263, No. 4, February 5, 1988, pp. 1719-1725, The American Society for Biochemistry and Molecular Biology, Inc.	
	C89	PREISSNER, et al., "Evaluation of the Immotopics Human FGF-23 (C-term) ELISA Kit", <i>Clinical Chemistry</i> , Vol. 52, No. 6, Suppl. S, June 2006, p. A174.	
	C90	REITER, et al., "Engineering Interchain Disulfide Bonds into Conserved Framework Regions of Fv Fragments: Improved Biochemical Characteristics of Recombinant Immunotoxins Containing Disulfide-stabilized Fv", <i>Protein Engineering</i> , 1994, Vol. 7, No. 5, pp. 697-704.	

Examiner Signature		Date Considered	
---------------------------	--	------------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: <u>October 27, 2009</u> (use as many sheets as necessary)		Application Number	10/500,296
		Filing Date	January 6, 2003
		First Named Inventor	Yuji YAMAZAKI
		Art Unit	1644
		Examiner Name	Zachary S. SKELDING
Sheet	7	of	8
		Attorney Docket Number	081356-0218

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	C91	RIECHMANN, et al., "Reshaping Human Antibodies for Therapy", <i>Nature</i> , March 1988, Vol. 332, No. 6162, pp. 323-327.	
	C92	RIMINUCCI, et al., "FGF-23 in Fibrous Dysplasia of Bone and its Relationship to Renal Phosphate Wasting," <i>J. Clin. Invest.</i> , 2003, Vol. 112, No. 5, pp. 683-692.	
	C93	ROWE et al., "Candidate 56 and 58 kDa Protein(s) Responsible for Mediating the Renal Defects in Oncogenic Hypophosphatemic Osteomalacia", <i>Bone</i> , Vol. 18, No. 2, February 1996, pp. 159-169, Elsevier.	
	C94	ROWE et al., "MEPE, a New Gene Expressed in Bone Marrow and Tumors Causing Osteomalacia", <i>Genomics</i> , Vol. 67, No. 1, July 1, 2000, pp. 54-68, Academic Press.	
	C95	SHIBATA et al., "Monoclonal Antibodies Against Recombinant Human FGF-23", <i>J. Am. Soc. Nephrol.</i> , September, 2002, Vol. 13, p. 499A (SU-P0151).	
	C96	SHIMADA, T. "FGF23 and Phosphorus metabolism", <i>The Japanese Society for Bone and Mineral Research (JSBMR)</i> , Annual Meeting of the JSBMR, 23 rd Program, June 20, 2005, Vol. 23, pp.121. (English translation provided)	
	C97	Shinichi Aizawa, "Biotechnology Manual Series 8, Gene Targeting," Yodosha, 1995	
	C98	SHIRAHATA et al., "E1A and ras Oncogenes Synergistically Enhance Recombinant Protein Production under Control of the Cytomegalovirus Promoter in BHK-21 Cells", <i>Biosci. Biotech. Biochem.</i> , Vol. 59, No. 2, February 1995, pp. 345-347, Japan Society For Bioscience, Biotechnology, and Agrochemistry.	
	C99	SHULMAN, et al., "A Better Cell Line for Making Hybridomas Secreting Specific Antibodies", <i>Nature</i> , November 1978, Vol. 276, No. 5685, pp. 269-270.	
	C100	STROM et al., "Pex gene deletions in Gy and Hyp mice provide mouse models for X-linked hypophosphatemia", <i>Human Molecular Genetics</i> , Vol. 6, No. 2, February 1997, pp. 165-171, The Oxford University Press.	
	C101	SUNAGA, et al., "Efficient Removal of loxP-Flanked DNA Sequences in a Gene-Targeted Locus by Transient Expression of Cre Recombinase in Fertilized Eggs," <i>Molecular Reproduction and Development</i> , 1997, Vol. 46, pp. 109-113.	
	C102	TATSUMI et al., "Identification of Three Isoforms for the NA ⁺ -dependent Phosphate Cotransporter (NaPi-2) in Rat Kidney", <i>The Journal of Biological Chemistry</i> , Vol. 273, No. 44, October 30, 1998, pp. 28568-28575, The Society for Biochemistry and Molecular Biology, Inc.	
	C103	TOMIZUKA, et al., "Double Trans-Chromosomal Mice: Maintenance Of Two Individual Human Chromosome Fragments Containing Ig Heavy And Antibodies", <i>Proc Natl Acad Sci U.S.A.</i> , 2000, Vol 97, No. 2, pp.722-727.	

Examiner Signature		Date Considered	
---------------------------	--	------------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: <u>October 27, 2009</u> (use as many sheets as necessary)		Application Number	10/500,296
		Filing Date	January 6, 2003
		First Named Inventor	Yuji YAMAZAKI
		Art Unit	1644
		Examiner Name	Zachary S. SKELDING
Sheet	8	of	8
		Attorney Docket Number	081356-0218

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	C104	URAKAWA, et al., "Klotho Converts Canonical FGF Receptor into a Specific Receptor for FGF23," <i>Nature</i> , December 2006, Vol. 444, pp. 770-774.	
	C105	VAN KROONENBERGH, et al., "Human Immunological Response to Mouse Monoclonal Antibodies in the Treatment or Diagnosis of Malignant Diseases," <i>Nuclear Medicine Communications</i> , 1988, Vol. 9, pp. 919-930.	
	C106	WHITE, et al., "Autosomal Dominant Hypophosphataemic Rickets is Associated with Mutations in FGF23," <i>Nature Genetics</i> , November 2000, Vol. 26, pp. 345-348.	
	C107	WHITE et al., "Molecular cloning of a novel human UDP-GalNAc: polypeptide N-acetylgalactosaminyltransferase, GalNAc-T8, and analysis as a candidate autosomal dominant hypophosphatemic rickets (ADHR) gene", GENE, ELSEVIER BIOMEDICAL PRESS, Amsterdam NL, vol. 246, no. 1-2, April 2000, pp. 347-356.	
	C108	WILKINS et al., "Oncogenic Osteomalacia: Evidence for a Humoral Phosphaturic Factor", <i>Journal of Clinical Endocrinology and Metabolism</i> , Vol. 80, No. 5, October 22, 2000, pp. 1628-34, The Endocrine Society.	
	C109	WRIGHT, et al., "High Level Expression of Active Human Alpha-1-Antitrypsin in the Milk of Transgenic Sheep", <i>Bio/Technology</i> , September 1991, Vol. 9, No. 9, pp. 830-834.	
	C110	YAMAMOTO, et al., "The Role of Fibroblast Growth Factor 23 in Hypophosphatemia and Abnormal Regulation of Vitamin D Metabolism in Patients with McCune-Albright Syndrome," <i>J. Bone Miner. Metab.</i> , 2005, Vol. 23, pp. 231-237.	
	C111	YAMASHITA, et al., "Identification of a Novel Fibroblast Growth Factor, FGF-23, Preferentially Expressed in the Ventrolateral Thalamic Nucleus of the Brain," <i>Biochemical and Biophysical Research Communications</i> , 2000, Vol. 277, pp. 494-498.	
	C112	YAMAZAKI, et al., "Anti-FGF23 neutralizing antibodies show the physiological role and structural features of FGF23", <i>Journal of Bone and Mineral Research</i> , Vol. 23, No. 9, Sept 2008, pp. 1509-1518.	
	C113	YELTON, et al., "Fusion of Mouse Myeloma and Spleen Cells", <i>Current Topics in Microbiology and Immunology</i> , 1978, Vol. 81, pp. 1-7.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.